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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,700	10/18/2001	Roger Samzelius	P01,0353	8626

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EXAMINER

WEISS JR, JOSEPH FRANCIS

ART UNIT	PAPER NUMBER
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3743

57

DATE MAILED: 12/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/982,700

Applicant(s)

SAMZELIUS, ROGER

Examiner

Joseph F Weiss Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Claim Rejections - 35 USC § 103

I. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

II. Claims 1-4, 7-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ward et al (US 6360740).

Ward substantially discloses the instant application's claimed invention to include a tubing system (8), a pneumatic unit (6), a sensor system (22/24) consisting of at least one flow meter and a pressure meter (see col. 5 lines 36-38), a control unit (30) having a first determination unit connected to said sensor system that is fully capable of receiving a measurement signal representing at least one parameter (30, note col. 5 lines 49-54), and fully capable of determining a first respiration indication signal based upon the parameter, a comparator (30, note col. 5 lines 55-57, optimization) connected to the first determination unit that is fully capable of receiving said first respiration indicating signal with a trigger requirement (the programmed data input by the physician), and generating a comparator output (the results of the comparison of physician input data to the measures data that results in optimization of operation of the device) indicative of whether or not the trigger requirement has been met and a signal generator (30, note its in two way electronic communication within itself and the various components of the system) supplied with the comparator which is fully capable of generating a trigger signal for controlling triggering respiratory phases dependent on comparator output, but does not explicitly disclose an excitable cell detector (18) adapted to detect excitable cell signals related to the respiration of the user, a second

determination unit (26) supplied with said excitable cell signals which determines a second respiration indicator signal based upon excitable cell signals and an adapter unit (30) supplied with said second respiration indicator and connected to said comparator, said adaptation unit adapting said trigger requirement dependent on said second respiration indicator signal and supplying said trigger requirement to said comparator (note col. 5 lines 55-57), one of ordinary skill appreciating that the control unit being a programmable based system all of the functions disclosed are indicative of various aspects of its program, i.e. algorithms and thus serving as the basis of obvious equivalency of structure since they are same functions and capabilities as set forth by applicant

In regards to claim 9, the pre-programmed values of the ventilator serve as a trigger for operation of the device & as such are "trigger sensitive and/or enabled" and the process of optimization of the device's operation relative to the feedback obtained from a user via the first and second respiration signals & adaption unit allows for any change of any values that serve as a trigger.

In regards to claim 11, the excitable cell signal detector (18) is disclosed as a nerve signal sensor (See col. 4 line 66-col. 5 line 3).

In regards to claim 12, the excitable cell signal detector (18) is disclosed as a phrenic efferent signal sensor (See col. 4 line 66-col. 5 line 5).

In regards to method claims 1-4 & 7, one of ordinary skill in the art would appreciate that the method steps claimed in the instant application would naturally flow from the device disclosed in the prior art as noted above and therefore are rejected herein above with respect to claims 8-15.

III. Claims 5-6 & 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sinderby (US 5671752).

In regards to claim 13, Ward substantially discloses the instant application's claimed invention, but does not explicitly disclose a muscle signal sensor. However, Sinderby disclose such (See Fig 8). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Sinderby and used them with the device of Ward. The suggestion/motivation for doing so would have been to optimize sensitivity and accuracy of ventilation support by direct diaphragm monitoring. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

In regards to claim 14, the suggested device discloses the muscle signal sensor as being a diaphragm electromyography sensor

In regards to claim 15, the suggested device discloses the sensor as comprising a esophageal catheter having an array of sensing electrode.

In regards to method claims 5-6, one of ordinary skill in the art would appreciate that the method steps claimed in the instant application would naturally flow from the device disclosed in the prior art as noted above and therefore are rejected herein above with respect to claims 8-15.

Response to Arguments

1. Applicant's arguments filed 14 Oct 03 have been fully considered but they are not persuasive.

In regards to the 35 USC 112 rejections of definity, applicant's amendment is proper and responsive, therefore the rejections are withdrawn.

In regards to the request for clarification, applicant has commented on the record that the apparent redundancy is not such, but that he specifically intends a specific and more narrow trigger definition, and not a broader triggering definition that is inherent in using the term trigger. Applicant's comments seem to indicate the examiner was giving the definition a narrow read, but the plain language of the request for clarification is to the converse. Examiner thanks applicant for pointing out this same more narrow usage of triggering is used by applicant in the corresponding method claims, hence the record is now clear that applicant intends this more narrow species of usage of triggering in both apparatus claims 9-10 and corresponding method claims 2-3.

In regards to the 35 USC 103 obviousness type rejection, applicant's amendment is proper and responsive but does not resolve the issue, in effect applicant's "Request for reconsideration" in light of the prima facie findings IAW 35 USC 103 based upon substantial evidence on the record as a whole and IAW 5 USC 555 (APA) cannot be persuasive.

The stand alone 103 rejection does not need to resort to Sinderby, hence applicant's "assumption is in error. What applicant means by the ordinary skill statement is that applicant is only positively claiming a processor and that all the other language applicant sets forth about how the device operates does not serve as a patently distinguishing positive limitation in an apparatus. Thus by dint of disclosing a processor Ward meets all the structural limitations applicant positively sets forth. "Hinting" at algorithms, programming etc in the claims does not result in a positive claiming of patently distinguishing structure. Applicant's attempts to characterize the

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clarion that is the rejection as unclear and speculative are in error and the product of the false presumption that something additional is being positively claimed. There is no need to have motivation, disclosure or a teaching for something that is not positively claimed. Claim it first then argue it, not the opposite as the record currently stands. Any argument that the current claims do positively the operation of the processor must be supported by legally binding authority, not mere bias speculation.

Conclusion

2. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F Weiss Jr. whose telephone number is 703-305-0323. The examiner can normally be reached on M-F, 8-4.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 703-308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Jfweiss
12/18/03


Aaron J. Lewis
Primary Examiner